

Table 14.2.2.8.1.1 Summary of evaluation of changes in vaginal biocenosis by scheduled visit and treatment (PPS)

Scheduled visit	Presence of Candida species in cultivation result	Statistics	IMUNOR	PLACEBO
Visit 2		N	52	21
	Yes	n (%)	13 (25.0)	2 (9.5)
	Candida albicans	n	13	2
	No	n (%)	39 (75.0)	18 (85.7)
	Not done/available	n (%)		1 (4.8)
Visit 3		N	51	21
	Yes	n (%)	3 (5.9)	1 (4.8)
	Candida albicans	n	3	1
	No	n (%)	12 (23.5)	6 (28.6)
	Not done/available	n (%)	36 (70.6)	14 (66.7)
Visit 4		N	49	19
	Yes	n (%)	12 (24.5)	4 (21.1)
	Candida albicans	n	10	4
	Candida glabrata	n	1	
	Other non-albicans Candida sp.	n	1	
	No	n (%)	36 (73.5)	15 (78.9)
	Not done/available	n (%)	1 (2.0)	
Visit 5		N	47	19
	Yes	n (%)	3 (6.4)	
	Candida albicans	n	1	
	Candida glabrata	n	1	
	Candida krusei	n	1	
	No	n (%)	11 (23.4)	4 (21.1)
	Not done/available	n (%)	33 (70.2)	15 (78.9)
EOS		N	52	21
	Yes	n (%)	16 (30.8)	6 (28.6)
	Candida albicans	n	14	6
	Candida glabrata	n	1	
	Candida albicans, Candida glabrata	n	1	
	No	n (%)	32 (61.5)	14 (66.7)
	Not done/available	n (%)	4 (7.7)	1 (4.8)

% = Percentage of subjects out of N; EOS = End of Study visit; N = Total number of subjects at visit; n = Number of subjects within specified category; PPS = Per Protocol Set; sp. = species.

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Table 14.2.2.8.1.2 Shift table of changes in vaginal biocenosis by scheduled visit and treatment (PPS)

Scheduled visit	Shift from baseline in presence of Candida species in cultivation result	Statistics	IMUNOR	PLACEBO
Visit 3		N	51	21
	Yes → No	n (%)	3 (5.9)	1 (4.8)
	Yes → Yes	n (%)	1 (2.0)	
	No → No	n (%)	9 (17.6)	5 (23.8)
	No → Yes	n (%)	2 (3.9)	1 (4.8)
	Missing	n (%)	36 (70.6)	14 (66.7)
Visit 4		N	49	19
	Yes → No	n (%)	11 (22.4)	1 (5.3)
	Yes → Yes	n (%)	2 (4.1)	
	No → No	n (%)	25 (51.0)	13 (68.4)
	No → Yes	n (%)	10 (20.4)	4 (21.1)
	Missing	n (%)	1 (2.0)	1 (5.3)
Visit 5		N	47	19
	Yes → No	n (%)	4 (8.5)	
	Yes → Yes	n (%)	1 (2.1)	
	No → No	n (%)	7 (14.9)	4 (21.1)
	No → Yes	n (%)	2 (4.3)	
	Missing	n (%)	33 (70.2)	15 (78.9)
EOS		N	52	21
	Yes → No	n (%)	5 (9.6)	1 (4.8)
	Yes → Yes	n (%)	7 (13.5)	1 (4.8)
	No → No	n (%)	27 (51.9)	12 (57.1)
	No → Yes	n (%)	9 (17.3)	5 (23.8)
	Missing	n (%)	4 (7.7)	2 (9.5)

% = Percentage of subjects out of N; EOS = End of Study visit; N = Total number of subjects at visit; n = Number of subjects within specified category; PPS = Per Protocol Set.

The shift value is missing if the baseline and/or scheduled assesment result is missing.

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Table 14.2.2.8.2.1 Summary of evaluation of changes in vaginal biocenosis by scheduled visit and treatment (FAS)

Scheduled visit	Presence of Candida species in cultivation result	Statistics	IMUNOR	PLACEBO
Visit 2		N	90	46
	Yes	n (%)	19 (21.1)	6 (13.0)
	Candida albicans	n	18	4
	Candida glabrata	n		2
	Candida albicans, Candida glabrata	n	1	
	No	n (%)	70 (77.8)	39 (84.8)
	Not done/available	n (%)	1 (1.1)	1 (2.2)
Visit 3		N	88	46
	Yes	n (%)	7 (8.0)	2 (4.3)
	Candida albicans	n	7	2
	No	n (%)	20 (22.7)	11 (23.9)
	Not done/available	n (%)	61 (69.3)	33 (71.7)
Visit 4		N	83	43
	Yes	n (%)	20 (24.1)	11 (25.6)
	Candida albicans	n	17	10
	Candida glabrata	n	2	1
	Other non-albicans Candida sp.	n	1	
	No	n (%)	58 (69.9)	31 (72.1)
	Not done/available	n (%)	5 (6.0)	1 (2.3)
Visit 5		N	79	42
	Yes	n (%)	8 (10.1)	3 (7.1)
	Candida albicans	n	5	2
	Candida glabrata	n	1	1
	Candida krusei	n	1	
	Other non-albicans Candida sp.	n	1	
	No	n (%)	19 (24.1)	11 (26.2)
EOS	Not done/available	n (%)	52 (65.8)	28 (66.7)
		N	90	46
	Yes	n (%)	22 (24.4)	13 (28.3)
	Candida albicans	n	20	11
	Candida glabrata	n	1	1
	Candida krusei	n		1
	Candida albicans, Candida glabrata	n	1	
	No	n (%)	59 (65.6)	32 (69.6)
	Not done/available	n (%)	9 (10.0)	1 (2.2)

% = Percentage of subjects out of N; EOS = End of Study visit; FAS = Full Analysis Set; N = Total number of subjects at visit; n = Number of subjects within specified category; sp. = species.

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Table 14.2.2.8.2.2 Shift table of changes in vaginal biocenosis by scheduled visit and treatment (FAS)

Scheduled visit	Shift from baseline in presence of Candida species in cultivation result	Statistics	IMUNOR	PLACEBO
Visit 3		N	88	46
	Yes → No	n (%)	3 (3.4)	1 (2.2)
	Yes → Yes	n (%)	2 (2.3)	
	No → No	n (%)	17 (19.3)	10 (21.7)
	No → Yes	n (%)	5 (5.7)	2 (4.3)
	Missing	n (%)	61 (69.3)	33 (71.7)
Visit 4		N	83	43
	Yes → No	n (%)	13 (15.7)	3 (7.0)
	Yes → Yes	n (%)	4 (4.8)	2 (4.7)
	No → No	n (%)	44 (53.0)	27 (62.8)
	No → Yes	n (%)	16 (19.3)	9 (20.9)
	Missing	n (%)	6 (7.2)	2 (4.7)
Visit 5		N	79	42
	Yes → No	n (%)	4 (5.1)	
	Yes → Yes	n (%)	2 (2.5)	1 (2.4)
	No → No	n (%)	15 (19.0)	11 (26.2)
	No → Yes	n (%)	6 (7.6)	2 (4.8)
	Missing	n (%)	52 (65.8)	28 (66.7)
EOS		N	90	46
	Yes → No	n (%)	8 (8.9)	1 (2.2)
	Yes → Yes	n (%)	7 (7.8)	5 (10.9)
	No → No	n (%)	50 (55.6)	30 (65.2)
	No → Yes	n (%)	15 (16.7)	8 (17.4)
	Missing	n (%)	10 (11.1)	2 (4.3)

% = Percentage of subjects out of N; EOS = End of Study visit; FAS = Full Analysis Set; N = Total number of subjects at visit; n = Number of subjects within specified category.

The shift value is missing if the baseline and/or scheduled assesment result is missing.

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